*Minutes*
**American Fisheries Society – Fish Culture Section**
**Working Group on Aquaculture Drugs, Chemicals, and Biologics (WGADCB)**
*August 3, 2011---Bozeman Montana*

**Attendees**

Jesse Trushenski (SIUC)
Patricia Gaunt (MSU/College of Vet. Medicine)
Ken Cain (Univ. of Idaho)
Karen Steveson (Univ. of Idaho)
Randy MacMillan (NAA/ClearSprings Food)
Lester Khoo (AVMA/MSU)
Steve Sharon (WY Game and Fish/DAWG)
Mike Mason (IA DNR)
Doug Burton (ID DF&G)
Wade Cavender (Utah Div. of Wildlife)
Chris Wilson (Utah Div. of Wildlife)
John Kaufman (Oregon DF&G)
John Kerwin (Washington DF&W/PNFHPC)
Mike Matthews (Florida Bass Cons. Center)
Mark Haffley (PA B&F Commission)
Mark Gaikowski (USGS/UMESC)
Jim Bowker (USFWS/AADAP)
Dave Erdahl (USFWS/AADAP)
Dan Carty (USFWS/AADAP)
Bonnie Johnson (USFWS/AADAP)
Molly Bowman (USFWS/AADAP)
Tom Bell (USFWS/AADAP)
Niccole Wandelear (USFWS/AADAP)
Guppy Blair (USFWS/ID FCH)
Sonya Mumford (USFWS/Olympia FCH)
Julia Pridgeon (USDA, ARS, AAHRL)
Phil Klesius (USDA, ARS, AAHRL)

Scott Melton (FDA/CVM)
Eric Landis (FDA/CVM)
Cindy Burnsteel (FDA/CVM)
Dorothy Bailey (FDA/CVM)
Kristen Beckhorn (FDA/CVM)
Holly Erdely (FDA/CVM)
Amy-Lynn Frankshun (FDA/CVM)
Stacey Gore (FDA/CVM)
Yin Guo (FDA/CVM)
Stuart Jeffery (FDA/CVM)
Adrienne Kurtz (FDA/CVM)
Dottie McAdams (FDA/CVM)
Sanja Modric (FDA/CVM)
Eric Silberhorn (FDA/CVM)
Cindy Stine (FDA/CVM)
Holly Zahner (FDA/CVM)
Dick Endris (Intervet/Schering-Plough)
Palma Jordan (Intervet/Schering-Plough)
Kaska Cox (Intervet/Schering-Plough)
Greg Bergt (Pennfield Animal Health)
Tom Goodrich (AQUI-S New Zealand)
Hugh Mitchell (Aquatic Life Vet Services)
Jim Bracket (Western Chem/Syndel Labs)
Jerry Bommer (Frontier Scientific)
Roger Yant (Hybrid Catfish Co.)
Tom Schoenfeld (Lucigen Corp)

Jen Matysczak (FDA/CVM)
Jennifer Love (FDA/CVM)

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**Call to Order**
JT called the meeting to order at 10:42 am. She introduced the other WGADCB co-chairs in attendance—JB, LK, MG, SS, RM, Scott LaPatra, and Andy Lazur (SL and AL not in attendance).

**Review and Accept Minutes**
Minutes from the previous WGADCB meeting (February 28, 2011, New Orleans LA) were published in the AFS Fish Culture Section and AADAP newsletters. Minutes were accepted as published by unanimous consent.

In an effort to more broadly disseminate meeting minutes, they will also be sent out on the WGADCB email list (includes all who have attended a WGADCB meeting in the past) and to Gary Jensen (JSA). In addition, JB will contact the AFS Fish Health Section (FHS), JT will contact the U.S. Aquaculture Society (USAS), and LK will contact the American Veterinary Medical Association to see if WGADCB minutes can be disseminated via their listservs as well. JB sent meeting minutes Dr. Jerri Bartholomew to disseminate via the FHS listserv. JT sent a request to USAS President Michael Schwarz to request permission to distribute via the USAS listserv. President Schwarz advised that the USAS Board doesn't typically send their own meeting minutes out to the membership, so there isn't a precedent or mechanism by which to do this easily, but he will ask the rest of the Board whether they feel it is appropriate to provide WGADCB updates to their membership. LK received the following response from the AVMA AqVMC: "The AqVMC appreciates the request from the WGADCB for having the minutes of the WG distributed through AquaVetMed e-News and on the AVMA website, but unfortunately it was felt that this was not the appropriate venue for conveying the business issues of other organizations. The minutes will continue to be a made available to the AqVMC as part of the liaison report and can be disseminated to interested veterinarians as requested." LK remains hopeful that a link to the FCS or AADAP websites could be created on an AVMA-sponsored page to make it easier for those interested to get WGADCB updates and information.

**Old Business**
New WG Co-chairs: new representatives Andy Lazur (USAS representative) and Scott LaPatra (FHS representative) were recognized.

Restructuring the WGADCB – Following recent discussion among the current co-chairs and other WGADCB participants, JT suggested restructuring the WG to have 1 or 2 Chair-persons and an advisory committee (consisting of all other current co-chairs). There was some discussion as to whether an advisory panel was still necessary at all, but FCS by-laws require that all ad-hoc committees consist of at least three committee members.

JT suggested another alternative, which would be to restructure the WGADCB as an AFS Task Force. In 1993, AFS created a TF on Fishery Chemicals consisting of two subcommittees: Fish Management Chemicals Subcommittee (FMCS) and Aquaculture Chemicals Subcommittee (ACS). Based on annual reports to AFS ExCom dating back several years, it appears that the ACS is largely non-functional (though the FMCS is quite active). There is also some confusion within AFS about the roles of the ACS unit and the WGACB. JT suggested that we ask AFS to dissolve the ACS and re-envision the WGADCB as a separate AFS TF. There was some concern whether the WG could continue to function as it has been if it is an AFS TF (e.g., would participants need to be AFS members? Would we have the autonomy to function as we do now? Would the AFS President appoint the Chairperson?). JT indicated that regardless of whether the WGADCB stayed a FCS ad-hoc committee or was elevated to a TF, the WG Chair has to be an AFS member. JT will ask AFS if it is possible to disband the ACS unit (leaving the FMCS

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as its own TF) make the WGADCB a parallel AFS TF with certain conditions (e.g., participants not required to be AFS members). JT has contacted AFS President Bill Fisher, outlining this issue, and has requested feedback regarding whether the ACS could be disbanded, what constraints would be placed on the WGADCB if it were elevated to the level of an AFS Task Force, etc. President Fisher is in the midst of making committee appointments at this time, and has indicated that he will take some time to discuss this issue with the AFS leadership before responding. Being part of the bigger AFS will likely give the WG more gravitas within AFS and help better connect the WGADCB with stakeholders and other AFS units.

Revising the Guide to Using Drugs, Biologics and Other Chemicals in Aquaculture: The Guide was developed with the intention that it would be periodically reviewed and revised. JT and JB have received revision suggestions and intend to revise the Guide accordingly. There was some discussion about establishing a formal review process to include time schedule for review (e.g., annually at the beginning of the year), external review of revised sections by contributing authors, review by external reviewers, review of current drug labels to ensure the Guide reflects the current content, etc. JT and JB will update the Guide based on suggestions provided to-date The revised Guide is now complete and ready for posting/distribution (document has been sent to AADAP and FCS webmasters for immediate posting). Additionally, the treatment calculator has been updated to include INAD drugs, and a second Excel 97-2003 version of the calculator has been created for greater accessibility. MG will put together a straw-dog template of when and how to review the Guide.

AFS Policy Statement on the need for an immediate-release fish sedative: The period for AFS members to provide comments on the PS is closed; very few comments were received; most communications were to congratulate the group on this effort. JB and JT revised the document to incorporate the few substantive suggestions received, and worked with the AFS Resource Policy Committee to draft a Motion that the Governing Board approve to present the final PS to the full AFS membership for approval. JT indicated that AFS wants PS that are useful, that we should promote this PS for educational/informational purposes, and solicit ideas on how AFS should best use this PS for these purposes. A call-to-vote notice will be published in the November issue of Fisheries, and the electronic vote to approve the PS will be completed by mid-December. Based on feedback to-date, it is anticipated that the vote will be positive and a new AFS PS will be ratified by the end of the year.

Listening Session with CVM: JT commented that feedback from participants following the LS were encouraging, that the group worked collegially to identify areas where the efficiency of the drug approval process could be improved, and that the CVM Teams that participated in-person or via telecom provided clarification on some issues and seemed very willing to explore alternative methods to improve efficiencies. The following Action Items were discussed and all agreed that ad-hoc committees would be assembled, determine a course of action that could be achieved within a 2-3 month period, and following this self-determined workplan, begin to address their action items in anticipation of the next LS:

1. How to share discoveries/breakthroughs – concern that this information is not disseminated as broadly as it should, particularly to new drug sponsors.
    a. JB will see if this information can be included in the AADAP Newsletter
    b. It was suggested that somebody work with sponsors/researchers and put together a 15-min presentation on discoveries/breakthroughs to be presented at future Drug Approval Coordination Workshops.
    c. MG suggested that CVM develop a “Lessons Learned” document and that all involved in the process be given an opportunity to contribute.

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i. DC suggested that going through study deviations and CVM response letters may be a good place to start.
ii. CB commented that CVM provided a list of common protocol or final study report comments to AHI (Animal Health Institute), that compiling this list was a lot of work, that some sponsors apparently did not read this document, and that CVM could not post this document on their website, but that AADAP could post it on their website. JB will check out AHI's website to see if it was posted. AHI has a great link on their website: Research and Resources. Under this is another link: Points to Consider. Under this link, there are several informative documents. However, the information presented by CB at the Workshop is not listed.
iii. CB commented that this information can be pulled from public INADs but will be difficult to assemble an all-inclusive list due to confidential INADs (unless the sponsor is willing to work collaboratively on this effort).
iv. JM suggested a joint presentation by CVM and non-CVM staff might be beneficial to share this information with others. MG and JB will investigate what type of information might best be presented and try to identify the target audience.

d. JM hopes that Guidance Document #61 will include some of this information.

2. Data-mining to determine what study variables are the most important and contribute substantively to the decision-making process
    a. Dan Carty will compile a list of data/variables that may be important and questions that could be addressed through a data-mining approach.
3. More effective use of peer reviewed literature
    a. Eric Landis, Holly Zahner, and an AADAP representative (Niccole Wandelear) will assemble an ad-hoc committee and establish criteria to describe when peer reviewed literature (or grey literature such as reports) can be used in the body of evidence to support safety or effectiveness (i.e., reduce the number of required pivotal efficacy or TAS studies). A rubric, highlighting critical elements for evaluating/weighting the quality of peer reviewed literature, will be developed.
4. More effective use of INAD Data:
    a. Susan Storey, Tom Bell, and Bonnie Johnson will assemble an ad-hoc committee and establish criteria to describe when INAD data can be used in the body of evidence to support safety or effectiveness (i.e., reduce the number of required pivotal efficacy or TAS studies). Similar to #3 above, a rubric will be developed. A telecon was convened between Tom, Bonnie, Susan, Jen Matysczak, and Jim Bowker to discuss more efficient use of INAD data. Susan said that she has been working on developing a list of ideas/suggestions to more efficiently use INAD data, and will provide this list to Tom and Bonnie by the end of the year for their review and comment.
5. Changes to MUMSA to revise Index Drug labels to modify the "NOT APPROVED BY FDA" language:
    a. OMUMS agrees with the necessity of making this change and is currently working to find the appropriate mechanism/vehicle to make this statutory change.
    b. OMUMS will keep the group apprised of their progress making this change
6. Identifying a 'worst-case scenario' to streamline residue depletion studies and determination of withdrawal times:
    a. MG and Holly Erdely will assemble an ad-hoc committee, investigate whether there is such a thing as 'worst-case scenario' for residue depletion, and if there is, investigate

whether a conservative withdrawal period can be established to reduce the number of residue depletion studies conducted under worst-case scenario conditions.

7. List of questions new sponsor might like to ask CVM during product development meetings:
    a. Dick Endris and Jenn Love (CB will discuss this with the Project Management Team to see if JL can participate) will form an ad-hoc committee and assemble a list of questions that should be provided to new sponsors or research partners that will likely expedite their drug approval efforts (e.g., ultimate goal is for an all-fish approval, but an approval for all freshwater salmonids would be acceptable as a start).
8. Investigate whether drug method transfer trials can be conducted outside the CVM Office of Research:
    a. Karen Ekelmanwill investigate and provide the group with an answer. Karen Ekelman provided the following response: **Question**: Public partners often develop methods for aquaculture drugs and transfer them to sponsors. Sponsors schedule traditional method trials for aquaculture and other animal drugs with ONADE, including involvement of OR. Because these trials are complex and time-consuming, OR can only handle 2 – 3 per year. Sponsors that have more than one drug undergoing review at CVM will prioritize the methods they want to take through the ONADE/OR method trial process, which can mean that aquaculture drugs are given low priority by sponsors and thus take much longer to complete this approval requirement than traditional drugs. Is there a way to get aquaculture drug methods approved without going through the standard ONADE/OR method trial? **Answer**: Yes. Any drug sponsor can elect to conduct a method transfer trial for the *determinative procedure* using only contract laboratories (the developing laboratory and several naïve laboratories). Using contract laboratories eliminates the need to fit the transfer trial into OR's schedule but it also eliminates strategic input from the ONADE method coordinator, the ONADE analyst assigned to interface with the sponsor's laboratories and OR in the traditional method trial paradigm. This is an option regardless of the species for which the approval is sought (major or minor species; fish or terrestrial). The *confirmatory procedure* must be trialed at a government laboratory (usually CVM OR) to ensure its suitability for any legal actions associated with drug misuse following approval (*i.e.,* prosecutions for violative residues). Because many methods now link determination with confirmation, limiting OR participation to the confirmatory procedure may provide only minimal benefit over a traditional method trial. Please contact Dr. Lynn Friedlander, Leader, Residue Chemistry Team (lynn.friedlander@fda.hhs.gov) if you have additional questions.
9. Survey to provide additional information to the Environmental Safety Team:
    a. The ES Team would like additional information about water use and production densities at different hatcheries around the country (e.g., total water flow through the hatchery as a function of fish density, flow through treated tank/raceway, how many tanks/raceways of fish would be treated at one time).
    b. Steve Sharon will be initiating a fish production survey, and has agreed to include questions in the fish production survey to gather information of interest to the ES Team. Steve will assemble an ad-hoc committee to help formulate the questions. Randy MacMillan has agreed to assist on behalf of the private sector.
10. All Other Things:
    a. JT and JB will assemble ad-hoc committees to:
        i. Develop a decision tree template to improve efficiencies re: generating data to support a claim of safety and effectiveness (similar to the approach used to use

preliminary data to support reducing the number of fish tissues to collect during eugenol TAS studies).

ii. Provide justification to establish fish species grouping that make more sense than cold, cool, and warmwater fish species (e.g., salmonids and non-salmonids). Jennifer Matysczak suggested the use of salmonid/non-salmonid classification as an approach for the next product development meeting for sponsors interested in pursuing an "all freshwater fish" claim.

iii. Provide scientific justification to group fish pathogens (Eric Landis, Lester Khoo, and Scott LaPatra will assemble an ad-hoc committee to try to address this issue)

iv. Define what information must be provided to CVM when studies are conducted that are not 100% GLP-compliant (i.e., anything deviating from GLP requirements should be itemized/discussed in the Final Study Report). It is generally agreed that anything not in compliance with GLP simply needs to be fully documented. Jennifer Matysczak subsequently suggested that if anyone is planning to do a TAS study with GLP deviations, they should discuss the GLP deviations with CVM before the study is run (e.g. identify such deviations from GLP in a protocol submitted for review). Certain deviations or a significant number of deviations may not be acceptable.

11. Comments to the Group that might improve the next LS:
    a. Eric Dubbin will provide comments that might improve the next LS.

Development of Expertise Groups: Researchers directly involved in aquaculture drug approval research often do not have sufficient background in related scientific disciplines (e.g., fish health, histology, toxicology, physiology) to be able to adequately address concerns that may be expressed by CVM reviewers. It was suggested that the WGADCB survey its members to identify the scientific disciplines where we have expertise, identify the scientific disciplines where we lack expertise, and work to correct these deficiencies by identifying experts who may be willing to participate in the WGADCB. JT will develop an online survey and JB distribute it via the WGADCB email list. Survey was developed and distributed to the WGADCB participants. To date, results have been compiled from 35 respondents (see attached). The survey (or perhaps a slightly modified version) will also be sent by JT to FHS and USAS to cast a broader net for expertise and involvement in the WGADCB.

The meeting was adjourned at 11:30 am.

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